REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow. This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claims 1, 3-10, 12-14 are requested to be cancelled. Claims 16, 25 and 34-36 are currently being amended. After amending the claims as set forth above, claims 16-22, 25-29 and 34-43 are now pending in this application. No new matter was added.

I. The Non-Enablement Rejection Should Be Withdrawn

Claims 1, 3-10, 12-14, 16-22, 25-29 and 33-43 are rejected under § 112, ¶ 1 as being non-enabled. This rejection is respectfully traversed.

The Office Action notes that the present specification does not provide specific foaming parameters to obtain the claimed pore distribution. Applicants submit that once the structure of the claimed biomember was described to a person of ordinary skill in the art, then this person of ordinary skill in the art would be able to perform the foaming method to obtain the claimed biomember with the claimed porosity distribution without undue experimentation.

For example, column 7, lines 50-62 of U.S. Patent No. 6,340,648 ("US '648") describes the process conditions which determine the final pore size in a sintered article. Thus, US '648 is evidence that one of ordinary skill in the art would know how to select the foaming conditions to obtain a sintered article with a desired pore size.

One example showing how to make the claimed biomember is provided below. Hydroxyapatite particles having a diameter of about 0.4μm, ion exchange water functioning as dispersing agent, polyethylene imine functioning as cross-polymerizable organic substance are mixed in the polymerization ratio of 10:8:1 so as to produce a mixture. Such a mixture is mixed by means of a ball mill for 10 hours so as to make a slurry. As a foaming agent,

polyoxyethylene lauryl ether of 1.1 wt.% is added into the slurry, and then mechanically stirred for 15 minutes, so that the slurry may contain sufficient foams. Next, as a cross linking agent, epoxy compound of 2.0 wt.% is added into the slurry containing the foams, and continuously stirred. After that, the slurry is poured into a die, and then cross-polymerized so as to be cured. Thereafter, it is removed from the die and then dried. It is further sintered at 1200°C so as to produce a hydroxyapatite porous body. This porous body has a porosity of 75%, and a mean pore diameter of 190μm. Among the pores having pore diameters larger than the mean pore diameter, the number of the communicating pores having diameters more than 5μm is 11.2 on the average. The diameter of the communicating pores is 42μm on the average. One or more of the communicating pores have a diameter of 110μm or more on the average. About 18% of the area in cross of the porous body is open. The compressive strength of the porous body is 12Mpa.

The process of the example above uses conventional ceramic fabrication steps, including mixing the apatite and a cross-polymerizable substance (polyethylene imine), forming a slurry, adding a foaming agent (polyoxyethylene lauryl ether) to the slurry, foaming the slurry, adding a cross linking agent (epoxy) to the slurry, curing the slurry in a die, and then drying and sintering the dried composition to form the porous body.

Likewise, US '648 discloses similar, conventional ceramic fabrication steps, which are listed in col. 5, lines 1-11 and in col. 5, lines 10-35 (i.e., Example 1) of US '648. Specifically, Example 1 of US '648 describes a method of forming a porous sintered body where hydroxyapatite powder is used as a raw material powder, ion exchange water is used as a solvent, polyethylene imine is used as the cross-polymerizable substance, epoxy is used as a cross linking agent, and polyoxyethylene lauryl ether is used as a foaming agent.

Thus, the example of making the claimed biomember uses the same starting materials and methods as Example 1 of US '648. This demonstrates that only standard ceramic fabrication steps are used to form the claimed biomember. Therefore, as shown by the example above, if the novel structure of the claimed biomember is described to a person of ordinary skill in the art, then this person of ordinary skill in the art would be able to perform the ceramic fabrication method to obtain the claimed biomember with the claimed porosity

distribution without undue experimentation using information available in the prior art, such as the information available in US '648 and other ceramic member fabrication references. A patent application need not teach, and preferably omits, what is known in the art. MPEP §2164.01. Since general ceramic fabrication methods are well known in the art, there is no need to disclose such methods in the present application. Applicant respectfully requests a withdrawal of the rejection.

II. The Prior Art Rejections Should Be Withdrawn

1. Rejection over WO 93/04013

Claims 36-43 were rejected as being unpatentable under §103(a) over WO 93/04013 in view of Chistolini or Itokazu. This rejection is respectfully traversed.

Page 7, paragraph 2 of the Office Action indicates that the rejections of independent product claims 1, 16 and 25 over WO 93/04013 were withdrawn because these product claims recite that the mean pore diameter is between 50 and 800 microns. Independent claim 36 has been amended to also recite that the mean pore diameter is between 50 and 800 microns. Thus, Applicant respectfully submits that claims 36-43 are patentable over WO 93/04013 in view of Chistolini or Itokazu at least for the same reason as claims 16 and 25.

2. Rejection over US '648

Claims 1, 3-10, 12-14, 16-22, 25-29 and 36-43 were rejected as being unpatentable under §103(a) over US '648 in view of Chistolini or Itokazu. This rejection is respectfully traversed.

Claims 1, 3-10, and 12-14 have been cancelled, rendering the rejection moot.

Independent claims 16 and 25 recite a biomember which includes a compact member (i.e., a dense part in claim 25) and a porous member (i.e., a porous part in claim 25). An example of such structure is shown in Figures 15 and 16 of the present application. Specifically, Figures 15 and 16 and pages 41-43 and 47-49 of the present application describe a porous member 22, 32 integrally formed with a compact member 21, 31. The compact

member 21, 31 integral with the porous member 22, 32 together constitute a biomember, such as an artificial bone, having an excellent strength.

In contrast, US '648 does not teach or suggest a combination of a compact member with the porous member. The entire sintered body of US '648 comprises a porous member. Thus, the sintered body of US '648 lacks a compact member of claim 16 or the dense part of claim 25.

Applicant notes that Col. 4, lines 13-19 of US '648 states:

> In a preferred potassium phosphate sintered body according to this invention, the skeleton part of the calcium phosphate porous sintered body consists a substantially densed calcium phosphate sintered body, and its surface part has fine irregularities or a layer consisting of the calcium phosphate porous sintered body. Accordingly, the specific surface area of the calcium phosphate porous sintered body is 0.1 m^2/g or more. (emphasis added).

The above portion of US '648 means that the porous sintered body of US '648 contains a skeleton part and pores between the skeleton part. The skeleton part and the pores together make up the porous sintered body. The "densed calcium phosphate sintered body" refers to the skeleton part of the porous sintered body. Thus, "densed calcium phosphate sintered body" is different from the compact member of claim 16 and is different from the separate dense part of claim 25 of the present application.

In other words, claims 16 and 25 of the present application recite (i) a compact member or dense part and (ii) a porous member or part. The claimed porous member or part contains a skeleton part and pores. In contrast, US '648 only teaches the porous member or part which contains the skeleton (i.e., densed) part and pores. Furthermore, a second porous layer may be present in the pores of the porous sintered body of US '648. However, neither the porous sintered body nor the porous layer located in the pores of the porous sintered body of US '648 corresponds to the compact member of claim 16 or the dense part of claim 25 of the present application.

The attached exhibit shows an exemplary embodiment of the claimed biomember based on Figure 16 of the present application. The biomember contains a compact member or densed part 31 having, for example, no pores, which is integral with the porous member or part 32. The member 31 and member 32 together constitute a biomember having an excellent strength.

Figure A of the attached exhibit is an enlarged view of Figure 16 showing the porous member 32 having a skeleton part 1 and pores 2 according to a non-limiting example of the claimed invention.

Figure B is an enlarged view showing a porous body having a skeleton part 3, pores 4 and porous layers 5 in the pores 4 according to U.S. '648.

In both Figures A and B, the skeleton parts 1, 3 consist of densed or compact calcium phosphate sintered body. In Figure B, the surface part of the densed calcium phosphate sintered body or skeleton 3 has the layer 5 consisting of the calcium phosphate porous sintered body. However, as shown in Figure B, the porous sintered body of US '648 lacks the compact member or densed part that is different from the porous member or part, as recited in claims 16 and 25 of the present application.

Thus, US '648 does not disclose a combination of a compact member and a porous member. US '648 teaches that the porous layer 5 is provided on the surface part of the skeleton 3 in a porous body. The porous layer 5 is positioned within the pores 4, so that the strength of the porous body is not remarkably improved.

III. Conclusion

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment,

to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 10/12/04

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